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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,368	10/26/2001	James P. Hoeffler	INVIT1100-2	2504

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EXAMINER

COOK, LISA V

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/18/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/035,368

Applicant(s)

HOEFFLER ET AL.

Examiner

Lisa V. Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 September 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-24 and 48-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 18-24 and 48-70 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

## DETAILED ACTION

### *Amendment Entry*

1. Applicant's preliminary amendment filed 10/26/01 in paper #6 is acknowledged. In amendment-B filed therein claims 1-17 and 25-47 were cancelled without prejudice. While claim 24 was amended and new claims 51-70 were added. Currently claims 18-24 and 48-70 are pending and under consideration.

### *ELECTION OF SPECIES*

2. This application contains claims directed to the following patentably distinct species of the claimed invention: The claims are directed to a method of comparing protein expression in at least two cell populations via multiple antibody utility (claims 18-24 and 48-70). However the method includes a plurality of patentably distinct inventions wherein materially different substances/antibodies are employed. Each substance/antibody acts as a ***binding agent*** in the claimed method but are diverse compositions having independent characteristics, which are not totally encompassed by all antibodies. Accordingly the substances/antibodies act independently and distinctly in the method. Claims 19, 20, and 51-59 are drawn to different antibody characteristics/ diverse substances. Therein applicant is required to select one for consideration.

As to *group I*: claims 18-19, 21-24, 48-50, and 60-70 are drawn to a method of comparing protein expression in two or more populations of cells via *uncharacterized* antibodies.

As to *group II*: claims 18, 20, 21-24, 48-50, and 60-70 are drawn to a method of comparing protein expression in two or more populations of cells via *recombinant* antibodies.

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As to *group III*: claims 18, 21-24, 48-50, 51-52, and 60-70 are drawn to a method of comparing protein expression in two or more populations of cells via *multispecific/bispecific* antibodies.

As to *group IV*: claims 18, 21-24, 48-50, 53-54, and 60-70 are drawn to a method of comparing protein expression in two or more populations of cells via *antigen-binding antibody fragments*.

As to *group V*: claims 18, 21-24, 48-50, 55, and 60-70 are drawn to a method of comparing protein expression in two or more populations of cells via *IgG, IgM, IgE, or IgA* antibodies.

As to *group VI*: claims 18, 21-24, 48-50, 56, and 60-70 are drawn to a method of comparing protein expression in two or more populations of cells via *chimeric* antibodies.

As to *group VII*: claims 18, 21-24, 48-50, 57, and 60-70 are drawn to a method of comparing protein expression in two or more populations of cells via *humanized* antibodies.

As to *group VIII*: claims 18-19, 21-24, 48-50, 58, and 60-70 are drawn to a method of comparing protein expression in two or more populations of cells via *single chain* antibodies.

As to *group IX*: claims 18-19, 21-24, 48-50, 59, and 60-70 are drawn to a method of comparing protein expression in two or more populations of cells via *diabodies* antibodies.

3. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claims 18, 21-24, 48-50, 60-70 are generic.

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4. Applicant is advise that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



**Lisa V. Cook**

CM1-7B17

12/4/02



**LONG V. LE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

12/16/02